

## **REMARKS**

### **1. Status of Claims**

No claims are canceled, added, or amended.

### **2. Sections 1-15 of the Office Action: Rejection of Claims 1, 5, 7, 9, 10, 16, 17, 19, 22, 25, and 27-30 under 35 USC §103 in view of US 2003/0032859 to Belson and U.S. 5,486,127 to Wolfe**

*Belson* provides an endoscopic “guide” formed of a freely reconfigurable set of segments which are asserted by the Office Action as having a ball-and-socket mating arrangement (FIG. 7A), and wherein the segments can be rigidly locked in place by applying vacuum along the segments (see, e.g., paragraphs [0023], [0025], [0072], etc.). *Wolfe* describes segments which bear “keys” (e.g., at 6 and 6B of FIG. 4) which prevent relative rotation between segments (see, e.g., column 1 lines 13-19). The Office Action asserts that:

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the balls and sockets of *Belson* with the projections and slots, as taught by *Wolfe*, to control the amount of displacement about the axis of the male and female connectors (column 3, lines 15-25).

(Page 3, also page 6.)

Kindly reconsider and withdraw these rejections, since an ordinary artisan who had no knowledge of the claimed invention, but who knew of *Belson* and *Wolfe*, would not truly contemplate modifying *Belson* to add projections and projection-receiving slots as recited in claims 1 and 16.

*Firstly*, it does not seem feasible that an ordinary artisan who sought to improve upon *Belson* would really look to the field of toys, as in *Wolfe* -- which deals with a model of a dinosaur skeleton (see FIG. 1, also column 3 lines 40-41) -- for ideas on how to improve the *Belson* endoscope. As noted in MPEP 2141.01(a), to rely on a reference in an obviousness rejection, the reference must be analogous prior art:

The examiner must determine what is “analogous prior art” for the purpose of analyzing the obviousness of the subject matter at issue. “Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the

manner claimed." *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1397 (2007). Thus a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole.

Here, it cannot fairly be said that *Wolfe* is in the same "field of endeavor" as Applicants' or *Belson's* invention; it is a snap-connecting building toy (more particularly, a toy skeleton model), not an articulated medical probe to be manipulated within a body. It is also not seen how *Wolfe* is reasonably pertinent to the Applicants' claimed invention (at least without the use of hindsight), since *Wolfe* is intended to provide a snap-connecting building toy wherein connected parts are joined in rotation-free relation (see column 1 lines 6-23). Neither snap-connections, nor building toys, nor rotation-free connections are relevant; note that *Belson* neither has nor needs any of these features. More fundamentally, it simply cannot fairly be said that an ordinary artisan would have considered review of *Wolfe* when contemplating improvements for *Belson*, unless hindsight is used. (More generally, one seeking to improve a medical endoscope would simply not look to snap-together toy models unless hindsight is used.)

*Secondly*, even if one did consider the matter of *Wolfe*, given that *Belson's* segments are intended to be reconfigurable along any desired tortuous path (see *Belson's* FIG. 12 onward) and then locked into place when desired, *why would one incorporate Wolfe's tabs as asserted by the rejection, and thereby inhibit relative rotation between the segments?* The Office Action's asserted combination of features cannot be accomplished without limiting the angle of rotation of each *Belson* segment with respect to adjacent segments along the lengthwise axis of the *Belson* device, and such limitation would be counterproductive. More fundamentally, why would one even care if the *Belson* segments could rotate with respect to each other about the axis of the *Belson* device: once the vacuum is applied, so long as it's strong enough to hold the combined segments along a bent path along the lengthwise axis of the *Belson* device, it's strong enough to prevent rotation about this axis. Thus, the alleged benefit of "control[ling] the amount of displacement about the axis of the male and female connectors" is questioned, since it does not

seem necessary, and in fact seems negative insofar as it limits the angles between adjacent segments.

*Finally*, consider whether there is any reasonable expectation of success that one could even make the asserted modification – i.e., addition of projections to *Belson* – and still achieve the vacuum-tight seal between segments sought by *Belson*. Consider, for example, whether it seems possible to incorporate the *Wolfe* tabs into FIGS. 6A-8A of *Belson* and still obtain the “vacuum-locking” sought by *Belson*: it doesn’t seem that this could be done without impairing the vacuum-tight engagement between segment. Since the addition of the projections would thwart the vacuum formation needed to lock *Belson*’s device together (such locking being needed in order to obtain a lockable / usable invention), the addition cannot be obvious. See MPEP 2143.01 (subsection entitled “The Proposed Modification Cannot Render The Prior Art Unsatisfactory For Its Intended Purpose”).

In summary, since no ordinary artisan would consider use of *Wolfe*’s features without the benefit of hindsight; since there’s no apparent reason to, or benefit from, incorporation of the *Wolfe* tabs into *Belson*; and since inclusion of the *Wolfe* tabs into *Belson* would inhibit or destroy the “vacuum-locking” between segments sought by *Belson*, kindly withdraw the holding that such a combination is obvious.

**3. Sections 23-32 of the Office Action: Rejection of Claims 16-19, 22, 25, 26, 29, and 31 under 35 USC §102(e) (presumably §103(a) was intended?) in view of US 2004/0236316 to Danitz et al. and US 4,114,401 to Van Hoose**

Here the Office Action alleges:

The Applicant contends that the substitution of the joint of Danitz et al. with the universal joint of Van Hoose would disadvantageously decrease the degrees of freedom of Danitz. The Applicant refers to figures 1A-1B wherein cables connect the segments to allow free rotation. However, the substitution of Van Hoose would provide a more secure engagement between the male and female parts of the segments that would reduce the wear of the cables of Danitz, thus enhance the multiple degrees of freedom and strengthen the articulating angles of the segments. The Applicant contends that an ordinary artisan would not utilize an internal passage when using a Van Hoose joint since the projections are restrained within the slots. However, the projections of the pin within the Van Hoose joints are not restrained within the slots but are free to oscillate within the slots of the ball

such that a channel within the connected segments would not disrupt the movement of the pin and would allow communication between segments. The claim fails to specify the location of the lumen, however, Danitz teaches a lateral location of the passage within the segments that would allow a guide wire to pass therethrough and would not inhibit movement therein. The Applicant contends that the ball of Van Hoose fails to snap-fit within the socket, however, when pushed into the socket of the joint, the ball fits therein, thus creating a workable joint.

(Pages 13-14.) With respect, this reasoning is flawed and made in hindsight, and the rejections should be withdrawn. Consider that in *Danitz et al.*, one segment may rotate at nearly any angle with respect to an adjacent segment by extending the cable along one side of the device and simultaneously retracting the cable at the other side. Now mentally envision the operation of the *Van Hoose* arrangement as shown in FIG. 5: *Van Hoose*'s ball 114 / shank 140 / member 142 can only rotate

- (1) within the plane of the slot 120 (FIG. 6), with the ball 114 pivoting clockwise / counterclockwise in place within the socket 112, and with the shank 140 / member 142 "orbiting" the ball 144, and also
- (2) in a perpendicular plane, with the shank 140 / member 142 rotating about the ball 114 out of and into FIG. 5,

*but owing to the protrusion / pin 128's retention within slot 120, the ball 114 / shank 140 / member 142 cannot rotate along other planes.* It is therefore clear that the *Van Hoose* arrangement would substantially limit the degrees of freedom of *Danitz*: the ball 114 / shank 140 / member 142 is limited to rotation within the perpendicular planes. Incorporation of such features into *Danitz* would significantly limit *Danitz*'s ability to articulate along a tortuous path, such as that shown in FIG. 1F. Also consider that *Van Hoose* can only rotate until its projection "bottoms out" in the slot (until the projection interferes with the end wall of the slot). See, e.g., FIG. 5 of *Van Hoose*, and consider that ball 114 is limited in its ability to rotate within socket 112. This further limits bendability. The end effect is that it can take multiple segments of a *Danitz* / *Van Hoose* combination to achieve the same angle of bend that can be achieved in *Danitz* alone. This limitation in flexibility is seriously problematic when the device is used in sensitive soft tissue (see, e.g., FIGS. 13-14 of *Belson*): the device is supposed to conform to the path of the tissue,

rather than requiring the tissue to bend/stretch to accommodate the device (which can cause trauma).

For the foregoing reasons, *Van Hoose* is not capable of the same bending radii, within the same space, as *Danitz* – it cannot in fact “enhance the multiple degrees of freedom” of *Danitz* – and wouldn't be considered for incorporation into *Danitz* for this reason.

Further, the reasoning that one would incorporate the *Van Hoose* projection/slot into *Danitz* because this would “provide a more secure engagement between the male and female parts of the segments that would reduce the wear of the cables of *Danitz*” is flawed because:

- (1) the *Danitz* segments are in any event effectively “securely engaged” together by the multiple cables;
- (2) no “wear reduction” is avoided because one would still need the same number of cables in a *Danitz/Van Hoose* combination as in *Danitz* alone to achieve the same amount of maneuverability (and the tension needed on the cables to effect bends along the length of the device would not be any different); and
- (3) considering modern materials science (and resulting cable strength), and considering that the *Danitz* device is to be urged through passages in soft tissue, it's questionable whether the alleged “cable wear” is a problem in any event. (Note that none of the art of record mentions cable wear as a problem.)

In short, no ordinary artisan would truly consider making the asserted *Danitz / Van Hoose* combination owing to alleged segment engagement or cable wear considerations.

The rejection of claim 25 at Section 28 of the Office Action is also clearly erroneous, both legally and factually. The Office Action contends:

[T]he combination of *Danitz et al.* and *Van Hoose* discloses the claimed invention except for segments having lengths that are less than or equal to their diameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the segments having lengths that are less than or equal to their diameters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Initially, this is flawed because the stated rationale for the rejection does not adequately reflect the holding of *In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980), which stated

that “discovery of an optimum value *of a result effective variable in a known process* is ordinarily within the skill of the art” (i.e., it’s within the capabilities of an ordinary artisan to tinker with the parameters of known processes to fine-tune the processes). This is not the case here, where no process claims are in issue. Further, as noted in MPEP 2144.04, the Office may only pose an obviousness rejection based on a rationale in a prior court decision “if the facts in [the] prior legal decision are sufficiently similar to those in [the] application under examination”, which is not the case here. The case bears no factual similarities to *Boesch*, wherein the quantities of certain metals in an alloy needed to be optimized to minimize electron vacancies in the alloy. Finally, the erroneous reasoning underlying the rejection is shown by the fact that it doesn’t seem possible to adapt the *Van Hoose* arrangement to have the claimed dimensions. Stated simply, if the claimed matter is objectively considered without prejudice and without hindsight, it is seen that the prior art devices cannot be modified to meet the claim with any reasonable expectation of success.

#### **4. In Closing**

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

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